AUG 31 2000

K002379

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet, Inc.

Manufacturer: Biomet Merck LTD.
Murdock Road, Dorcan Industrial Estate, Dorcan
Swindon SN3 5HY, UK

Proprietary Name: M2a 28mm RingLoc® Acetabular Liner

Common or Usual Name: acetabular liner

Classification Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prothesis (888.3330)

Device Classification: Preamendment Class III

Device Product Code: 87 KWA

Device Description: The M2a-RingLoc® Metal-on-Metal Articulation is a slight modification from the M2a-Taper Metal-on-Metal Articulation cleared under 510(k) number K993438. The M2a-RingLoc® liner articulating surface is made from the same CoCrMo per ASTM F-1537 as the M2a-Taper Metal-on-Metal Articulation. Both devices (M2a-Taper and M2a-RingLoc®) contain the same geometry and dimensions as the predicate device thus not affecting the wear couple between the modular head and liner. The CoCrMo modular head to be used with the M2a-RingLoc® device is the same as that of the M2a-Taper device.

The modification resulting in a Special 510(k) submission was a change to the locking mechanism of the liner within the acetabular shell. The change was from a taper mechanism of the M2a-Taper to a RingLoc® mechanism in the M2a-RingLoc® design. The RingLoc® design utilized in the M2a-RingLoc® design is the same as that used in Biomet's RingLoc® ultra-high molecular weight polyethylene (UHMWPE) liners which were cleared in 510(k) number K920640.

The M2a-RingLoc® design contains a CoCrMo metal liner inlay compression molded into UHMWPE to be machined into the standard RingLoc® geometry. The CoCrMo liner inlay is machined and grit blasted on the backside similar to the M2a-Taper liner. The M2a-RingLoc® liners are machined to standard UHMWPE liner sizes and utilize the same outside geometry shells as the M2a-Taper. The M2a-RingLoc® device showed a greater pushout strength than that of the predicate device.

The modified acetabular liner may be used with any commercially available Biomet Ringloc® acetabular shell.

Indications for Use: 1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) rheumatoid arthritis; 3) correcion of functional deformity; 4) revision procedures where other treatment or devices have failed; 5) treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

Potential Risks:

1. Major surgical risks associated with anesthetic including: brain damage, pneumonia, blood clots, heart attack, and death.
2. Cardiovascular disorders including venous thrombosism pulmonary embolism, and myocardial infarction.
3. A sudden drop in blood pressure intraoperatively due to the use of bone cement.
4. Damage to blood vessels, hematoma, delayed wound healing and/or infection.
5. Temporary or permanent nerve damage may result in pain and numbness.
6. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene component of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.
7. Early or late postoperative, infection, and allergic reaction.
8. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock cause by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
9. Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.
10. Perarticular calcification or osseification, with or without impediment or joint mobility.
11. Inadequate range of motion due to improper selection or positioning of components.
12. Undesirable shortening of limb.
13. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
14. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
15. Fretting and crevice corrosion can occur at interfaces between components.
16. Wear and/or deformation of articulating surfaces.

17. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing or inadequate reattachment.
18. Problems of the knee or ankle of the affected limb or contralateral lib aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
19. Postoperative bone fracture and pain.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2000

Ms. Michelle L. McKinley
Regulatory Specialist
Biomet Inc.
P.O. Box 587
Warsaw, Indiana 46581

Re: K002379
Trade Name: M2a Ringloc® Acetabular Liner
Regulatory Class: III
Product Code: KWA
Dated: July 7, 2000
Received: August 4, 2000

Dear Ms. McKinley:

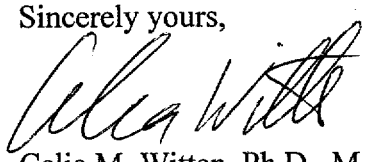
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002379

Device Name: M2a Ringloc® Acetabular Liner

Indications for Use: 1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) rheumatoid arthritis; 3) correction of functional deformity; 4) revision procedures where other treatment or devices have failed; 5) treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE OF ANOTHER PAGE IS NEEDED)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002379